SEP 17 1999

K991927/S1

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Bardick Ellam
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Date Summary was Prepared	
Name Of The Device	Medi-Test Combi 11
Identification Of Predicate Device(s)	Bayer Multistix 10SG Dia Strip System, Calif. Immuno Diagnostics
Description of The Device	The Medi-Test Combi 11 Reagent Strip for urinalysis is a dip-and-read test strip. The Medi-Test Combi 11 provides reagent areas on the strip for testing urine physiological parameters. The strip provides qualitative and semi-quantitative tests for specific gravity, leucocytes, glucose, ascorbic acid, protein, blood, nitrite, pH, ketones, bilirubin and urobilinogen by visual comparison with a color chart for each concentration range
Intended Use	The Medi-Test Combi 11 is a test strip for rapid determination of blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH, specific gravity and leucocytes in urine. The product is intended for use as an in vitro diagnostic aid using urine specimens for screening for diabetes, metabolic, abnormalities, liver diseases biliary and hepatic obstructions and diseases of the kidneys and the urinary tract.
Comparison of Device Characteristics to Predicate Device	The Combi 11 test strip is identical to the Dia Strip System's nine reagent tests and equivalent in performance to Bayer's Multistix 10SG. The Combi 11 adds the capability for screening for leucocytes and specific gravity of urine.

SUMMARY OF SAFETY AND EFFECTIVENESS	
Non-clinical Testing	Non-clinical testing of the Combi 11 was not submitted.
Clinical Testing	The Macherey-Nagel Combi 11 was investigated in actual clinical use by the Penn Elm Medical Group. The study was conducted during the normal course of providing patient care and included urinalyses for general physical assessment of asymptomatic patients and for patients presenting with specific diagnostic complaints. The study tested 100 randomly-selected urine samples from the clinic's patient population. The Penn Elm study indicates the Combi 11 had very similar results to the Bayer Multistix 10 for the reagent parameters.
Conclusion	Medi-Test Combi 11 has intended and technological characteristics in common to both predicate devices. A clinical study demonstrated the clinical effectiveness of the added reagent strip areas for screening for leucocytes and specific gravity in urine. Therefore, the Combi 11 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 1999

Macherey-Nagel-Duren
c/o Mr. Eduardo March, RAC
AAC Consulting Group
7475 Wisconsin Avenue
Suite 850
Bethesda, Maryland 20814

Re: K991927
Trade Name: Medi-Test Combi 11
Regulatory Class: I Product Code: JMA, JJB, JIN, JMT, JIR, CDM, CEN
Regulatory Class: II Product Code: JIN
Dated: August 11, 1999
Received: August 12, 1999

Dear Mr. March:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DRAFT

June 4, 1999

510(k) Number *(if known)*: K991927

Device Name: **Medi-Test Combi 11**

Indications for Use:

The Medi-Test Combi 11 Reagent Strip for Urinalysis is a dip-and-read test strip. The product is intended for use as an in vitro diagnostic aid using urine specimens for screening for diabetes, metabolic, abnormalities, liver diseases, biliary and hepatic obstructions and diseases of the kidneys and urinary tract.

The strip provides qualitative and semi-quantitative tests for specific gravity, leucocytes, glucose, protein, blood, nitrite, pH, ketones, bilirubin, ascorbic acid and urobilinogen by visual comparison with a color chart for each concentration range.

Jean Cooper
(Division Sign-Off)
Division of Clinical Lab[illegible]
510(k) Number K991927

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over-the-Counter Use:**
(Per 21 CFR 80.109)